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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,817	04/08/2005	Thomas A Alheidt	P-5856	9959

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

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04/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,817	Applicant(s) ALHEIDT ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6, 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/10/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Trenner (US Patent No. 4,781,684). Trenner discloses an IV flush syringe assembly (Figs. 1-14) comprising: a barrel (4) having an inside surface (30) defining a chamber (76) for retaining fluid, an open proximal end (6) and a distal end (8) including a distal wall (wall at 8) with an elongate tip extending distally therefrom having a passageway therethrough (46) in fluid communication with said chamber, said inside surface further including a contact area (32, 36) at the distal end of said barrel, a plunger (2) including an elongate body portion (18) having a proximal end (22), a distal end (near 20) and a flexible stopper (Figs. 11-14, 100) slidably positioned in fluid-tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber (col. 3, lines 35-40 disclose that the syringe is used for both aspiration and ejection of fluid) by movement of said stopper relative to said barrel, said elongated body portion extending outwardly from said open proximal end of said barrel (Fig. 12); wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with

said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (clearly the recess (32, 36) creates a portion of the surface with a roughened surface area, the roughened surface area therefore having higher coefficient of friction than the smooth surface area of the rest of the inside of the barrel. This roughened surface area has a higher coefficient of friction, as the coefficient of friction is dependent on the surface characteristics of each of the materials in contact with each other, therefore the roughened surface area provided by portion 32/36 inherently helps prevent further movement of the plunger; Fig. 13 discloses that the rib is received in the recess (32, 36) when the stopper is in contact with said distal wall. Furthermore, the contact area of 32/36 frictionally engages the stopper and frictionally holds the stopper in the deflected position, as friction is inherently present in the contact between the stopper's rib and the recess and plays a role in holding the position of the stopper in Fig. 13).

In reference to claim 21, Trenner discloses a needle assembly (10) including a cannula (10) having a proximal end, a distal end and a lumen therethrough (Fig. 1), and a hub (44) having an open proximal end containing a cavity and a distal end attached to said proximal end of said cannula so that said lumen is in fluid communication with said cavity, said needle assembly being removably attached to said tip of said barrel through engagement of said tip to said cavity so that said lumen is in fluid communication with said chamber (Figs, 1-3).

In reference to claim 22, Trenner discloses that the stopper is made from material selected from the group consisting of thermoplastic elastomers, natural rubber, synthetic rubber and combinations thereof (col. 7, lines 53-62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trenner (US Patent No. 4,781,684). Trenner discloses the device substantially as claimed including the contact area (32, 36) having an annular deformation (32 and 36 are a recess, i.e. an annular deformation). Trenner, however, does not disclose that there are a plurality of annular deformations. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to include multiple annular deformations, since it has been held that mere duplication of the essential working parts

of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trenner (US 4,781,684) in view of Lynn (US Patent No. 5,522,804). Trenner discloses the device substantially as claimed except for a tip cap and flush solution. Lynn, however, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), as better described by Col. 14, lines 20-30). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Trenner with a cap and the use of saline solution, as taught by Lynn, in order to seal the end of the syringe and to provide the syringe with a flushing solution, since the syringe of Palmer is structurally equivalent to a flushing syringe and is therefore perfectly capable of being used as a flushing syringe.

Response to Arguments

Applicant's arguments filed 2/10/2008 have been fully considered but they are not persuasive. While the examiner agrees that the syringe barrel is made of the same material in area 32/36 and the rest of the barrel outside this area, the examiner does not agree that these two areas have the same coefficient of friction. The coefficient of

friction is dependent on the types of materials in contact with each other, but this value is also dependent on the surface characteristics (such as rough vs. smooth) of the materials in contact with each other. For example, a greater force is needed to slide a material over a piece of rough granite (or other type of stone) than sliding a material over a piece of polished granite. The abstract of the journal article "Influence of self-affine surface roughness on the friction coefficient for rubbers" from the Journal of Applied Physics discloses that the coefficient of friction for a material increases proportionally with the increase in roughness of the surface of the material (Palasantzas, George. "Influence of self-affine surface roughness on the friction coefficient for rubbers". Journal of Applied Physics 94, 5652 (2003)). This abstract was found online at {<http://link.aip.org/link/?JAPIAU/94/5652/1>}. Therefore, the recess and the cornered portion on either side of the recess at contact area 32/36 provides a roughness to the surface in that contact portion of the syringe barrel that the stopper does not experience contacting in the remainder surface portions of the inside syringe barrel surface which is smooth. Therefore this contact area 32/36 provides an area with an increased coefficient of friction as compared to the smooth surface in the remainder of the barrel interior. It is the examiner's position, as presented above, that the contact area 32/36 frictionally engages the stopper (by frictionally engaging rib 108) and frictionally holds the stopper. As argued above, friction is inherently present between the contact area and the stopper portion 108 and therefore it can be said that the these two portions are frictionally engaged and frictionally retained.

Also, it is unclear how dependent claims 5 and 6, which refer to annular deformations/projections in the contact are, are different from the deformation/projection as taught by Trenner.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767